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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,963	10/12/2001	Michael T. Caplan	2002834-0115	2907

24280 7590 06/19/2002

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,963

Applicant(s)

Caplan et al.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-56 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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DETAILED ACTION

*Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10 and 29-41 are drawn to a method of treating rhionsinusitis or alleviating the symptoms of rhionsinusitis with an agent that permits the release of protein from the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- II. Claims 11-15 and 29-41 are drawn to a method of treating hemochromatosis or alleviating the symptoms with an agent that permits the release of protein from the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- III. Claims 16-22 and 29-41 are drawn to a method of treating Gitelman's syndrome or alleviating the symptoms of Gitelman's symptoms with an agent that permits the release of proteins from the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- IV. Claims 23-41 are drawn to a method of treating cystinuria or alleviating the symptoms of cystinuria with an agent that permits the release of proteins from the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.

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- V. Claims 42 and 43 are drawn to a method of treating any disease or clinical condition with an agent that permits the release of proteins from endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- VI. Claim 44 is drawn to a method of releasing a mis-assembled or mis-folded glycoprotein from the endoplasmic reticulum with an agent that decreases or inhibits the functional activity of UDP glucose:glycoprotein glycosyl transferase, classified in class 514, subclasses 431 and 468.
- VII. Claim 45 is drawn to a method of releasing a mis-assembled or mis-folded glycoprotein from the endoplasmic reticulum of a cell comprising the step of administering an agent that decreases or inhibits activity of the endoplasmic reticulum  $\text{Ca}^{++}$  ATPase, classified in class 514, subclasses 431 and 468.
- VIII. Claim 46 is drawn to a method of releasing a mis-assembled or mis-folded glycoprotein from the endoplasmic reticulum of a cell comprising the step of administering an agent that lowers the concentration of  $\text{Ca}^{++}$  in the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- IX. Claim 47 is drawn to a method of releasing a mis-assembled or mis-folded glycoprotein from the endoplasmic reticulum of a cell comprising the step of administering an agent that decreases or inhibits calnexin functional activity, classified in class 514, subclasses 431 and 468.

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- X. Claim 48 is drawn to a method of increasing the permeability of the apical surfaces of airway epithelial cells to a chloride ion with agent, classified in class 514, subclasses 431 and 468.
- XI. Claim 49 is drawn to a method of increasing the permeability of the apical surfaces of airway epithelial cells to a chloride ion comprising the step of administering an agent that decreases or inhibit the activity of UDP glucose:glycoprotein glycosyl transferase, classified in class 514, subclasses 431 and 468.
- XII. Claim 50 is drawn to a method of increasing the permeability of the apical surfaces of airway epithelial cells to a chloride ion comprising the step of administering an agent that decrease or inhibit activity of the endoplasmic reticulum Ca ++ ATPase, classified in class 514, subclasses 431 and 468.
- XIII. Claim 51 is drawn to a method of increasing the permeability of the apical surfaces of airway epithelial cells to a chloride ion comprising an agent that lowers the Ca ++ in the endoplasmic reticulum, classified in class 514, subclasses 431 and 468.
- XIV. Claim 52 is drawn to a method of increasing the permeability of the apical surfaces of airway epithelial cells to a chloride ion comprising an agent that decreases or inhibits calnexin functional activity, classified in class 514, subclasses 431 and 468.

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XV. Claim 53 is drawn to a method of screening candidate compounds to identify an agent, classified in class 435, various subclasses.

XVI. Claim 54 is drawn to a method of screening candidate compounds to identify an agent that inhibits the functional activity of UDP glucose:glycoprotein glycosyl transferase, classified in class 435, various subclasses .

XVII. Claims 55 and 56 are drawn to a composition comprising an aerosol formulation of thapsigargin, DBHQ or cyclopiazonic acid, classified in class 514, subclasses 431 and 462; class 424, subclass 45.

The seventeen inventions are independent and distinct, each from the other as they have acquired a separate status in the art as shown by their different classification and a separate subject matter for inventive effort. Further, a reference which anticipates any one of the above inventions would neither anticipate or make obvious of the other inventions. Each such invention is capable of supporting its own patent. For these reasons, the restriction requirement is proper.

To be complete, applicants' response must include a provisional election even though the requirement may be traverse.

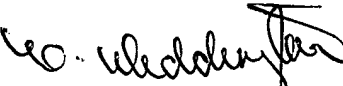
The applicants are required to elect a single invention for examination purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner K. Weddington whose telephone number is (703) 308-1235.

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**Kevin E. Weddington**  
**Primary Examiner**  
**Art Unit 1614**

K. Weddington

June 15, 2002